

# Standard emergency department care vs. admission to an observation unit for low-risk chest pain patients

## A two-phase prospective cohort study

IRB Proposal  
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### A. STUDY PURPOSE AND RATIONALE

#### Rationale:

The Centers for Medicaid and Medicare Services (CMS) are initiating a new standard for payment schemes for inpatient vs. outpatient care that differ dramatically in reimbursement. In particular, inpatient admissions that are less than two midnights in duration are to be reimbursed only as outpatient services. One way to address this and many other issues of cost and resource allocation is the development “short-stay units,” “assessment units,” or “observation units,” which are technically outpatient settings, where overall clinically stable patients can undergo further evaluation for a limited period of time (typically 24-48 hours). These units are intended to reduce costs, streamline and protocolize evaluations for common complaints (e.g. abdominal pain or chest pain), and allow for valuable emergency department resources to be more appropriately distributed. A literature review published in 2003 identified several benefits of such units from various studies primarily from the 1990s (“Table 1: A summary of the benefits of an assessment/admission ward with respect to certain groups of patients”). Notably, for patients presenting with low-risk chest pain, a study as early as 1994 showed that observation units were safe and cost effective (“Table 4: In-hospital resource utilization (unadjusted)”). In 2003, 12% of US hospitals were estimated to have ED observation units and by 2007, that estimate rose to 36%. Despite immense changes in the economics of the US healthcare system and despite the increasing prevalence of such units, there have been few recent studies attempting to replicate these results or test such units in other settings.

There is abundant anecdotal evidence from our internal medicine program housestaff that too many patients with low-risk chest pain are admitted to the hospital even after their diagnostic work-up has effectively ruled out an acute coronary syndrome by the time they are assigned a bed in the hospital and a medical team. Much of this is felt to be due to ED pressures to decide on a disposition before their change of shift, even if the ideal disposition hinges on results that are still pending over the next several hours. An observation unit could be one way to alleviate this problem by allowing ED staff to assign these patients to ED staff whose sole focus is the work-up of low-risk patients who require further testing before discharge from the ED.

**Table 1** A summary of the benefits of an assessment/admission ward with respect to certain groups of patients

| First author (year)  | Patient group                   | Summary of benefits gained from presence of an assessment/admission ward  |
|--|---------------------------------|---|
| Khan, SA (1997) <sup>58</sup>  | Elderly                         | Short stay ward can reduce some patients stay in hospital and reduce demand for in-patient places. Increased level of care for elderly patients.  |
| Beattie, TF (1993) <sup>44</sup><br>Biddulph, J (1984) <sup>59</sup> | Children                        | Children get comfortable beds more quickly. Improved awareness of simple pathology. Most children admitted to an observation unit were sent home without requiring hospital treatment. Observation easier and more efficient than if admitted fully to hospital.  |
| Ryan, J (1996) <sup>60</sup><br>Jones, A (1995) <sup>39</sup>        | Self Harm<br>Head injuries      | Most patients discharged next day without need for further follow up. Potential cost savings made. Observation ward offers safe and monitored area for recovery. Few patients require admission to other wards.   |
| Brown, SR (1994) <sup>61</sup><br>Gouin, S (1997) <sup>22</sup>      | Asthma                          | Number of inappropriate discharges decreased. An observation unit lowered the hospitalisation rate for children with asthma, yet there was an increased rate of repeat visits to the ED.  |
| Willert, C (1997) <sup>62</sup><br>Hutchins, CJ (1978) <sup>63</sup> | Gynaecology patients            | Holding room therapy for childhood status asthmaticus is beneficial both medically and cost wise. Of 408 patients admitted to one gynaecological unit, 56% were in hospital for less than 6 hours and a further quarter did not require hospital admission. Full staffing of a unit could release a number of beds for other selected work. |
| Gaspoz, JM (1994) <sup>64</sup><br>Goodacre, SW (2000) <sup>27</sup> | Chest pain                      | Short stay units prevent unnecessary long stays in hospital, and are safe and cost effective. There is insufficient evidence to say that an observation unit will improve outcomes if clinical practice is good. Not proven to be financially beneficial in the UK yet.   |
| Henneman, PL (1989) <sup>65</sup><br>Conrad, L (1985) <sup>66</sup>  | Abdominal conditions and trauma | Abdominal trauma and negative diagnostic peritoneal lavage can be safely managed in an observation unit. Patients with initial negative test results can be evaluated in observation units.   |
| Israel, RS (1991) <sup>67</sup>                                      |                                 | 72% of patients treated for pyelonephritis were successfully managed on an observation ward and were discharged early.  |

**Table 4. In-Hospital Resource Utilization (unadjusted)**

|  | COU<br>(n = 332)        | Wards<br>(n = 91)       | SDU<br>(n = 387)        | CCU<br>(n = 73)          |
|--|-------------------------|-------------------------|-------------------------|--------------------------|
| <b>Length of stay (days)</b>                           |                         |                         |                         |                          |
| Mean (SD)*   | 2.3 (3.4)               | 6.3 (6.8)               | 5.1 (6.1)               | 6.9 (6.7)                |
| Median (25th, 75th percentile)*                        | 1 (1, 2)                | 4 (2, 8)                | 3 (2, 6)                | 5 (2, 10)                |
| Minimal/maximal  | 1/35                    | 1/36                    | 1/64                    | 1/39                     |
| Initial Medicus score: median (25th, 75th percentile)† | 57 (54, 63)             | 34.5 (22, 49)           | 53 (46, 65)             | 75.5 (63, 90)            |
| Costs/patient (\$): median (25th, 75th percentile)*    | 1,318<br>(1,097, 2,141) | 3,589<br>(1,427, 6,279) | 2,749<br>(1,648, 5,509) | 5,598<br>(2,265, 14,432) |

\*Significantly lower for patients admitted to the coronary observation unit than for comparison patients admitted to the wards, to stepdown units or to the coronary care unit at the  $p < 0.0001$  level before and after multivariate analysis adjusting for triage, diagnoses and complications. †Significantly lower for patients admitted to the coronary observation unit than for comparison patients admitted to the coronary care unit at the  $p < 0.0001$  level before and after multivariate analysis adjusting for triage, diagnoses and complications but significantly higher than for comparison patients admitted to the wards ( $p < 0.0001$ ). The difference between patients admitted to the coronary observation unit and comparison patients admitted to stepdown units was of borderline significance (adjusted  $p < 0.06$ ). Missing data, Medicus scores: 21 patients admitted to the wards; 53 patients admitted to the coronary observation unit; 8 patients admitted to the stepdown unit; 1 patient admitted to the coronary care unit. CCU = coronary care unit; COU = coronary observation unit; SDU = stepdown unit.

Emergency medicine specialists have come to a general consensus on the criteria for observation unit care which are summarized in “Table 2. Principles of managing an ED observation unit.”

**Hypothesis:** Admitting patients with low-risk chest pain to an observation unit while acute coronary syndrome is being ruled out will reduce the number of unnecessary inpatient admissions without having a deleterious effect on health outcomes.

**Table 2. Principles of managing an ED observation unit**

1. Focused Patient Care Goals
2. Limited duration and intensity of services
3. Appropriate hospital location
4. Appropriate staffing
5. Providing ongoing care to an ED patient
6. Intensive review
7. Economical service

## B. STUDY DESIGN AND STATISTICAL ANALYSIS

### Subject Groups:

Risk stratification for patients presenting to the emergency department (ED) with chest pain is a critical component of the initial evaluation to guide diagnostic and therapeutic decisions in a timely manner. In 2012, Columbia University Medical Center/New York Presbyterian Hospital updated its guidelines for such patients in Clinical Pathways for ACS and Chest Pain. These guidelines will provide the key definitions needed for this study design, particularly indefining inclusion and exclusion criteria.

**Inclusion criteria:** Patients admitted to the adult emergency room complaining of chest pain and classified by an ED physician as ACS Level 3. ACS Level 3 is defined as normal or nondiagnostic ECG and/or atypical chest pain without alternative explanation.

**Exclusion criteria:** Patients with a concurrent medical or nonmedical problem that is expected to necessitate inpatient admission. Patients with an alternative explanation for chest pain, including but not limited to pulmonary embolism, pneumonia, recent trauma or surgery. Also exclude nursing home residents and patients in need of inpatient physical rehabilitation as the efforts to coordinate these dispositions often requires inpatient admission.

### Outcomes:

1. PRIMARY OUTCOME: Proportion of “unnecessary” inpatient hospital admissions: Defined as hospital admissions for acute coronary syndrome during which acute coronary syndrome is ruled out.
2. Proportion of “unnecessary” coronary catheterizations: Defined as coronary catheterizations that do not identify significant coronary artery lesions for which PCI or CABG would be recommended.
3. 30-day readmission rate to an emergency department.
4. 30-day all-cause mortality rate.
5. 30-day myocardial ischemic event rate: Include NSTEMI, STEMI, coronary catheterization, or positive stress test (i.e. a stress test with results requiring further evaluation with coronary catheterization).

## **Study Design:**

In phase one of the study, the first cohort of patients will serve as control subjects getting standard emergency department (ED) care as currently exists in our hospital. This will begin approximately 4 months prior to the planned opening of the observation unit. An emergency room physician will determine whether a patient meets inclusion criteria and lacks exclusion criteria (see above). Patients will then undergo standard care for acute coronary syndrome (level 3; see below for subject selection), including aspirin 325mg chewable, beta-blocker, and nitrates. Troponin and CPK levels will be assayed at 0, 4, and 8 hours from the time of ED admission. Serial ECGs will also be obtained at 0, 4, and 8 hours from the time of ED admission.

Inpatient admission to the hospital remains the prerogative of ED attendings, who may decide on admission at any point from the time of ED admission. As per current standard, patients who are determined to be suitable for inpatient admission will wait in the ED under care of usual ED staff until an accepting medical team is available in the hospital. Additional waiting time in the ED may occur as patients await an inpatient bed.

In phase two of the study, the second cohort of patients will serve as test subjects. Because the incidence of acute coronary syndrome is known to fluctuate somewhat with the time of the year, the approximate timing of the year of the recruitment of the second cohort will be matched to the timing of the first cohort. They will undergo the same initial ED evaluation as control subjects. But when ED physicians select ACS level 3 as a diagnosis, the patient will be assigned to the observation unit. In the observation unit, full time observation unit staff including physicians, nurses and physician assistants will adhere to current guidelines for ACS level 3 as described above. All ECGs and elevated cardiac enzymes will require a physician's interpretation. Final disposition (admission vs. discharge) will be the responsibility of the observation unit physician. Disposition can only be determined in the event that all 8 hours of serial ECGs and cardiac enzymes have been obtained and interpreted, or a patient may be admitted earlier.

Additional data to be collected at the time of ED admission or observation unit admission include: age, sex, race, education level, BMI, smoking status (never, former, current), previously known CAD, diabetes, hypertension, LDL, HDL, depression, and whether aspirin, beta blockers, or nitrates were administered during the emergency department or observation unit stay. This will be incorporated into ED physician notes as a series of checkboxes when the diagnosis ACS level 3 is selected.

## **Statistical Analysis:**

Outcomes of interest (described above) will be compared between the two cohorts via chi-square test of proportions. An analysis of variance will be performed for the baseline characteristics listed above with ANOVA testing.

## **Sample Size:**

Given an underestimation of the current proportion of unnecessary ACS level 3 admissions of approximately 10%, and given the expected proportion with initiation of the observation unit of 0%, (with assumed alpha 0.5 and power 0.8), approximately 92 subjects would be needed. Expecting a 20% rate of loss to follow-up, 115 subjects would need to be recruited into the study initially. We will begin the first phase of the study (the control cohort getting standard care in the ED approximately 4 months prior to the planned opening of the observation unit. Given the frequency of ACS3 admissions, this should be more than adequate to recruit the needed 115 patients for the first cohort. In the second phase, once the observation unit is operational, at the same time of year as the first cohort, patients will be recruited again until an equal number are recruited as in the first phase.

## **C. STUDY PROCEDURE**

Study procedures are identical to current standard of care for ACS level 3, including ECG and venous blood draws, and if recommended by a cardiologist, a stress test or coronary catheterization. There is no difference between types of procedures, frequency of procedures or any other pertinent differences in either cohort.

## **D. STUDY DRUGS**

Study drugs do not differ between test and control cohorts. They include aspirin 325 mg chewable, beta blockers and nitrates.

**E. MEDICAL DEVICE:** Not applicable.

**F. STUDY QUESTIONNAIRES:** Not applicable.

## **G. STUDY SUBJECTS**

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## **H. RECRUITMENT OF SUBJECTS**

Patients presenting to CUMC-NYP ED who are designated as ACS level 3 by ED physicians will be asked to participate in the study.

## **I. CONFIDENTIALITY OF STUDY DATA**

A unique code number will be used to identify all study participants. Data will be stored securely and only available for analysis by our investigators.

**J. POTENTIAL CONFLICT OF INTEREST:** None

**K. LOCATION OF STUDY:** Columbia University Medical Center—New York Presbyterian Emergency Department

## **L. POTENTIAL RISKS**

Potential risks of being in the test cohort include the possibility of missed diagnosis, particularly if observation unit staff members focus too narrowly on the predetermined diagnosis of ACS level 3. Therefore observation unit staff will be trained on the importance of remaining open-minded about the etiology of the patient's chest pain as well as attending to other issues that may develop during observation unit care. There is also a risk that if patients are more efficiently discharged that events occurring late in the clinical course may be missed when they otherwise would have been caught during a hospitalization.

## **M. POTENTIAL BENEFITS**

Benefits are expected to include fewer unnecessary admissions, shorter wait time for results, final assessments and appropriate disposition. Patients may also benefit by not being exposed to the inpatient environment which carries with it a risk of infection, deep vein thrombosis, deconditioning, and loss of work/psychosocial/economic stressors.

**N. ALTERNATIVE THERAPIES:** Not applicable

**O. COMPENSATION TO SUBJECTS:** None

**P. COSTS TO SUBJECTS:** None

**Q. MINORS AS RESEARCH SUBJECTS:** Not applicable

**R. RADIATION OR RADIOACTIVE SUBSTANCES:** Not applicable

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